DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Bulk Manufacturer of Controlled Substances Application: Navinta LLC

[Docket No. DEA-392]

ACTION: Notice of application.

DATES: Registered bulk manufacturers of the affected basic class, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before [INSERT 60 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

ADDRESS: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DRW, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: The Attorney General has delegated his authority under the Controlled Substances Act to the Administrator of the Drug Enforcement Administration (DEA), 28 CFR 0.100(b). Authority to exercise all necessary functions with respect to the promulgation and implementation of 21 CFR part 1301, incident to the registration of manufacturers, distributors, dispensers, importers, and exporters of controlled substances (other than final orders in connection with suspension, denial, or revocation of registration) has been redelegated to the Assistant Administrator of the DEA Diversion Control Division ("Assistant Administrator") pursuant to section 7 of 28 CFR part 0, appendix to subpart R.

In accordance with 21 CFR 1301.33(a), this is notice that on September 13, 2017, Navinta LLC, 1499 Lower Ferry Rd. Ewing, NJ 08618 applied to be registered as a bulk manufacturer for the basic classes of controlled substances:

Controlled Substance	**Drug Code**	**Schedule**
Pentobarbital	2270	II
4-Anilino-N-phenethyl-4-piperidine (ANPP)	8333	II
Levorphanol	9220	II
Remifentanil	9739	II
Fentanyl	9801	II

The company plans to initially manufacture API quantities of the listed controlled substances for validation purposes and FDA approval.

Dated: March 15, 2018

Susan A. Gibson,

Deputy Assistant Administrator.
Billing Code 4410-09-P

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